IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., CEREXA, INC., TAKEDA PHARMACEUTICAL COMPANY LIMITED, ALLERGAN USA, INC.,	)	
Plaintiff,	)	
v.	)	C.A. No. 15-018 (GMS)
APOTEX CORP., APOTEX INC. and SANDOZ INC.,	)	
Defendant.	)	

DEFENDANTS' JOINT ANSWERING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

Defendants Apotex Corp. and Apotex Inc. ("Apotex") and Sandoz Inc. ("Sandoz") (collectively "Defendants") respectfully submit this brief in response to the proposed claim constructions and arguments set forth in Plaintiffs'[1] August 19, 2016 Opening Claim Construction Brief (D.I. 110) ("Plaintiffs' Brief").[2]

The Court should adopt Defendants' proposed constructions, which adhere to the intrinsic evidence and controlling law because:

- Notwithstanding Plaintiffs' arguments to the contrary, the preambles of the asserted claims of the '175 patent directed to "a method for treating a bacterial infection" are not limiting;
- Plaintiffs' proposed construction of the term "a compound of the formula," as recited in claim 14 of the '175 patent, is an improper attempt to redraft this phrase as "a compound within the genus defined by the formula" and should be rejected;
- Apotex's proposed construction of the term "reactive derivative" in claim 14 of the '175 patent to mean "activated carbonyl derivative" is proper given Plaintiffs' disavowal during prosecution of any possible substituent groups at the R^1 position other than a phosphono group; and
- With respect to the '400 patent, based on the parties' agreed-to definition of the chemical name term in the asserted claims, Plaintiffs' alternative definition of that term incorporating the unnecessary phrase "Compound A," should be rejected. [3]

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[1] The Plaintiffs are Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Cerexa, Inc., Takeda Pharmaceutical Company Limited, and Allergan USA, Inc.

[2] Under the guise of "factual background," Plaintiffs improperly present argument, without any citations or support, as to why the patent claims at issue should not be considered obvious or anticipated. *See* Plaintiffs' Brief, pp. 4-5. Defendants will respond to these arguments at the appropriate time.

[3] As stated in Defendants' Joint Opening Claim Construction Brief (D.I. 109 at 2 n.3), the parties recognize the Court may not address indefiniteness challenges during the *Markman* proceedings. Defendants reaffirm their positions that certain asserted patent claims are indefinite, and reserve the right to challenge those claims as invalid for indefiniteness under 35 U.S.C. § 112. (*See* D.I. 102 - Final Second Amended Joint Claim Chart Ex. A at 10-11, 13.)

II. ARGUMENT

A. The '175 Patent – Disputed Claim Terms.[4]

1. The Preambles of Claims 5-7, 12, 15, 16, 20 and 21 of the '175 Patent are Non-Limiting and Duplicative.

Plaintiffs' position is that the method claims of the '175 patent require administration of the compounds to result in effective treatment. *See* Plaintiffs' Brief, p. 15 ("Plaintiffs have consistently sought to construe these claims as requiring the use of the compounds in a way that actually *treats* a bacterial infection") (emphasis in original). However, Plaintiffs allege that Apotex infringes the method claims, not when its ANDA product is an effective treatment, but when merely made, used, offered for sale, sold, and/or imported into the United States. *See* Plaintiffs' Initial Infringement Claim Chart, p. 2. In other words, Plaintiffs construe the claims narrowly for purposes of validity, then expansively for infringement, thus violating a principal axiom of patent law. *See W.L. Gore Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1279, 6 USPQ2d 1277, 1280–81 (Fed. Cir. 1988) ("Having construed the claims one way for determining their validity, it is axiomatic that the claims must be construed in the same way for infringement.").

Putting aside the inherent contradictory nature of Plaintiffs' argument, there is no reasonable basis for construing the preambles as limiting. The preambles: i) serve only to state the purpose of the intended method; ii) were not relied on during the prosecution history to distinguish prior art; and iii) are duplicative to the body of the claims. *See Symantex Corp. v. Computer Associates Intern., Inc.*, 522 F.3d 1279, 1288-89 (Fed. Cir. 2008). It is well settled

[4] In light of the dismissal of all claims, counterclaims, and affirmative defenses between Plaintiffs and Sandoz relating to the '175 patent (D.I. 111), Defendant Sandoz takes no position on the terms in dispute regarding the '175 patent.

that "[i]f the body of the claim sets out the complete invention, and the preamble is not necessary to give 'life, meaning and vitality' to the claim, 'then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.'" *Bristol-Meyers Squibb Co. v. Ben Venue Laboratories., Inc.*, 246 F.3d 1368, 1373-74 (Fed. Cir. 2001) (citation omitted). In this case, the body of the claims defines the complete invention with the preambles failing to further limit the scope.

In the *Bristol-Meyers Squibb* case, the Federal Circuit affirmed the following preamble as non-limiting: "[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity." *Id. at* 1374-77. Similar to the claim terms at issue in this case, the body of the claim in *Bristol* included language referring back to "said patient." *Id.* at 1372. However, the Federal Circuit concluded that the preamble merely stated an intended result. *Id.* at 1375. The steps of the method claim were "performed in the same way regardless whether or not the patient experiences a reduction in hematologic toxicity, and the language of the claim itself strongly suggests the independence of the preamble from the body of the claim." *Id.* Similarly, in the *Copaxone* case, Your Honor held that statements of intended outcome, such as "reducing [the] frequency of relapses," and "therapeutically effective," were non-limiting statements that had no bearing on the claimed methods. *See In re Copaxone 40 Mg*, 2016 WL 873062, *1, fn. 1-2 (D. Del. March 7, 2016).

The present Plaintiffs advance the same arguments rejected by the Federal Circuit in *Bristol-Meyers Squibb* and this Court in *In re Copaxone*. The preambles in this case merely state the intended purpose of the method claims and do not add any clarity or further steps to the body. The body of the claims, for their part, either explicitly or by reference to the independent claims, provide that an effective amount of a compound will be administered to a patient suffering from

a bacterial infection. Further, the parties have agreed that "effective amount" has its plain and ordinary meaning. *See* Final Second Amended Joint Claim Chart (D.I. 102), p. 4. But Plaintiffs retreat from that agreement, arguing instead that the "effective amount" in the body of the claim would not be understood by one of ordinary skill in the art as directed toward the bacterial infection, despite the fact that it is being administered to a patient "suffering from a bacterial infection." That argument is specious.

Plaintiffs further argue that, because the bodies of the claims refer to "the" bacterial infection, it follows that the references to "a" bacterial infection in the preambles serve as the antecedent basis. Again, the preambles in this case do not provide any further definition or clarity to the term "bacterial infection" in the body of the claim such that it should be considered a limitation. "A bacterial infection" is simply duplicative of "the bacterial infection." As the Federal Circuit has guided, "the purpose of a claim preamble is to give context for what is being described in the body of the claim; if it is reasonably susceptible to being construed to be merely duplicative of the limitations in the body of the claim (and was not clearly added to overcome rejection), we do not construe it to be a separate limitation." *Symantex Corp.*, 522 F.3d at 1288-89. In fact, "it is assumed that the preamble language is duplicative of the language found in the body of the claims or merely provides context for the claims, absent any indication to the contrary in the claims, the specification or the prosecution history." *Id.* at 1289.

In *Symantex*, the Federal Circuit found the preamble language "a method of screening the data as it is being transferred" to be duplicative of language in the body stating "receiving and screening the transferred digital data prior to storage…" *See id.* at 1289-90. Because these terms had essentially the same meaning, the Federal Circuit reversed the district court's determination that the preamble was limiting. *See id.* at 1290. In this case, Plaintiffs ask the Court to find the

term "a bacterial infection" in the preamble to be the antecedent basis for the term "the bacterial infection" in the body. Even more so than in *Symantex*, the preamble in the method claims of the '175 patent is duplicative and provides no clarity or meaning to the body of the claim.[5]

Importantly, the duplicative language in the preambles was not added to avoid prior art, and Plaintiffs do not make that argument. Nonetheless, Plaintiffs attempt to argue that the preambles should be considered as limiting the claims to instances in which the compound "actually *treats* a bacterial infection." *See* Plaintiffs' Brief, p. 15. The Federal Circuit has squarely rejected this approach:

> [plaintiff] would have us construe the claims as limited to those instances of practicing the claimed method that achieve the stated result for purposes of validity, but as encompassing all instances of carrying out the physical steps for purposes of infringement. Again, [plaintiff] cannot have it both ways.

Bristol-Meyers Squibb, 246 F.3d at 1376 (citation omitted). Here, Plaintiffs may not seek this narrow interpretation of the claims for purposes of validity, and then later seek to expand the claims for purposes of infringement. Plaintiffs have simply provided no reasonable basis for interpreting the preambles as limiting, and the general rule that such preambles are non-limiting should apply. *See* Defendants' Opening Brief (D.I. 109), pp. 8-9.

Finally, Plaintiffs misread Apotex's argument regarding the non-limiting preamble language. Plaintiffs state that Apotex's proposed construction would "include methods of using compounds in a patient who has a bacterial infection, but in which the compounds do not treat the infection, like using aspirin in a patient who has an upper respiratory infection and attendant

[5] For purposes of claims 7 and 21 of the '175 patent, it is even more clear that the preamble does not serve as an antecedent basis, as the body of each claim recites specific bacterial infections from which the patient is suffering, as opposed to the general language "bacterial infections" from the preambles.

fever. The aspirin may reduce the fever, but it does nothing to treat the infection." Plaintiffs' Brief at p. 15. Not so. Apotex's argument – consistent with the controlling law – is simply that the preamble is not *itself* a claim limitation; the preamble adds nothing meaningful to the rest of the claim language. Further, the "effective amount" limitation in the asserted claims shows Plaintiffs' argument lacks merit.

2. The term "reactive derivative" in process claim 14 of the '175 patent.

Plaintiffs' argument that there is no reason for a different construction of the claim element "a compound of the formula" is moot. Plaintiffs' argument is essentially predicated upon Apotex's proposed construction, which uses the exact same language as is recited in the claim term itself, namely "a compound of the formula." However, Apotex already stated in its opening claim construction brief that the parties agree that the express language of claim 14 requires the use of a compound of the formula, or within the genus defined by the depicted structural formula, wherein the symbols Q, R^1, and R^2 have the meanings listed in claim 1. Thus, and as acknowledged by Apotex, the language of the claim is clear – it recites a compound of the formula, or within the genus defined by the structural formula wherein the substituents have the same definitions as set forth in claim 1. The genus of possible structures is finite, and cannot differ from the scope of protection provided by use of the language explicitly set forth in the claim—language elected by the patentees themselves. Indeed, the parties have agreed upon the scope of this term. Accordingly, Plaintiffs' proposed construction, which seeks to redraft the patentees' own straightforward phrase "a compound of the formula" as "a compound within the genus defined by the formula," should be rejected because it adds nothing to the claim language as originally drafted, and therefore can provide no clarification or meaning to that term.

Next, Apotex's proposed construction of the claim term "reactive derivative" to mean "activated carbonyl derivative" is proper and consistent with the plain meaning of the claim term and the intrinsic evidence. While the specification does not explicitly define "activated carbonyl derivative," there are several disclosures limiting the reactive derivative to one which is located at the carboxylic acid. *See, e.g.*, col. 15, ll. 6-9; col. 21, ll. 16-17, 51-52, 58-59; col. 22, ll. 18-19. For example, the specification discloses that "compound (III) [the second compound recited in claim 14] as it is, its salt or its reactive derivative is used as an acylating agent for acylation of the amino group at the 7-position of amino compound." Col. 14, ll. 62-62. As a matter of chemistry, the use of the thiazole compound, the second compound in claim 14, as an acylating agent necessarily involves reaction of that compound through an activated form of its carboxyl group. A person of ordinary skill in the art would understand such a reactant to be an activated carbonyl derivative of the thiazole compound of claim 14. Further, a person of ordinary skill in the art would understand that the only way to react the two compounds recited in claim 14 to yield a compound of claim 1 would be via reaction through the activated carboxyl group.

Moreover, Apotex's construction is immutably supported by the prosecution history of the '175 patent. Claim 1, as originally filed, defined R^1 as "a phosphono group or a group convertible to a phosphono group." *See* '175 patent, PH, original application at 44. When the United States Patent and Trademark Office ("USPTO") rejected that definition of R^1 as unclear for several reasons, the patentees unmistakably changed the definition of R^1 to "phosphono, dialkoxy-phosphoryl, O-alkyl-phosphono, diaminophosphoryl, (amino)(hydroxy)phosphoryl, (alkoxy)(morpholino)phosphoryl or dihalophosphoryl." *See* '175 patent, PH, Oct. 9, 2001 Amendment and Remarks at 14, 17. The patentees supplemented their response with a declaration from Dr. Horibe, which was argued to show the superiority of a compound wherein

R^1 was a phosphono group (PO(OH)2) over a compound wherein R^1 was hydrogen. *Id.* at 19; *see also* Horibe Declaration.

In a Final Office Action dated November 28, 2001, the USPTO rejected claims 1 and 14 as obvious, but added that "claims limited to the phosph[ono] group are not rejected. However, the claims also cover the esters, the amide, an esteramide and the acid dihalide, and no testing had been done for such derivatives. Thus the testing is not commensurate with the scope of the claim, and hence the full scope of the claim has not been shown unexpected." '175 patent PH, 11/28/01 Final Rejection at 2. In their response, the patentees accepted the USPTO's argument, and again amended the definition of R^1 in claim 1, further limiting the definition of that substituent to be only a phosphono group (as the instant Defendants espouse). Accordingly, as a matter of prosecution history, the patentees explicitly defined R^1 as only a phosphono group, thus disavowing other alternatives. Plaintiffs also disavowed the possibility that the R^1 substituent as recited in claim 14 could be anything other than a phosphono group. The patentees voluntarily, and expressly, "limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips v AWH Corp.*, 415 F.3d, 1303, 1307 (Fed. Cir. 2005) (*en banc*).

The Court should thus construe the term "reactive derivative," to reflect Plaintiffs' disclaimer of any compounds wherein R^1 is anything other than "a phosphono group," and to ensure Plaintiffs do not recapture through claim construction subject matter clearly surrendered during prosecution. *See Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1376-77 (Fed. Cir. 1999). For these reasons, the Court should construe the term "reactive derivative" in claim 14 to mean "activated carbonyl derivative."

3. Claims 17 and 18 of the ’175 Patent.

As stated in Defendants’ Joint Opening Claim Construction Brief, Apotex’s position in regard to ’175 patent claims 17 and 18 is that they are indefinite. Based on the understanding that the Court may not consider such arguments during claim construction, Apotex reserves the right to raise this issue at the appropriate time.

B. The ’400 Patent – Disputed Claim Terms.

1. The Specification Does Not Define the Depicted Chemical Name in the Asserted Claims as “Compound A,” and to do so is Nonsensical.

Despite Plaintiffs’ claim to the contrary, the specification of the patent does not define the chemical name “(6R,7R)-7-[[(2Z)-2-(ethoxyimino)-2-[5-(acetamido)-1,2,4-thiadiazol-3yl]acetyl]amino]-3-[[4-(1-methylpyridinium-4-yl)-1,3-thiazol-2-yl]sulfanyl]-8-oxo-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate” as “Compound A.” Instead, the specification uses the term “Compound A” as a shorthand term to refer to that formula. As stated in Defendants’ Joint Opening Claim Construction Brief, it is not the purpose of claim construction to interpret terms used in the specification, but rather, to define disputed claim terms. *Every Penny Counts, Inc. v. Am. Express Co.*, 563 F.3d 1378, 1381 (Fed. Cir. 2009). An agreed upon chemical structure rather than “Compound A” defines the claimed chemical name. Thus, the Court should adopt the parties’ agreed-to chemical structure and reject Plaintiffs’ alternative definition including “Compound A.”

2. Defendants Reserve the Right to Argue the Phrase “up to about” in Claims 6-9 of the ’400 Patent Renders the Claims Indefinite.

As noted in the Defendants’ Joint Opening Claim Construction Brief and above for purposes of claims 17 and 18 of the ’175 patent, Defendants reserve the right to raise the issue of the indefiniteness of claims 6 through 9 of the ’400 patent at the appropriate time.

III. CONCLUSION

For all of the reasons set forth above and in Defendants' Joint Opening Claim Construction Brief, Defendants respectfully request that the Court adopt their proposed constructions of the disputed claim terms (to the extent the terms are not indefinite) as well as those constructions on which the parties have agreed.

Dated: September 9, 2016

Respectfully submitted,

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